

*Dnaye*

*AFI  
1723*

**PATENT**  
Attorney Docket No. 440446/Pall

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

BORMANN et al.

Application No. 09/806,322

Filed: March 29, 2001

For: BIOLOGICAL FLUID FILTER  
AND SYSTEM

Art Unit: 1723

Examiner: Krishman Menon

**TRANSMITTAL OF  
APPELLANTS' REPLY BRIEF**

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.193, appellants hereby submit Appellants' Reply Brief in triplicate.

The items checked below are appropriate:

**1. Status of Appellants**

This application is on behalf of ☒ other than a small entity or ☐ a small entity.

**2. Oral Hearing**

- ☐ Appellant requests an oral hearing in accordance with 37 CFR 1.194.  
☐ Appellant requested an oral hearing in accordance with 37 CFR 1.194 at the time appellant filed Appellant's Brief on Appeal.

**3. Extension of Time**

- ☐ Appellant petitions for a one-month extension of time under 37 CFR 1.136, the fee for which is \$110.00.  
☒ Appellants believe that no extension of time is required. However, this conditional petition is being made to provide for the possibility that appellants have inadvertently overlooked the need for a petition and fee for extension of time.

**Extension fee due with this request: \$**

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**4. Total Fee Due**

The total fee due is:

Request for Oral Hearing	\$ 0.00
Extension Fee (if any)	\$ 0.00

**Total Fee Due: \$**

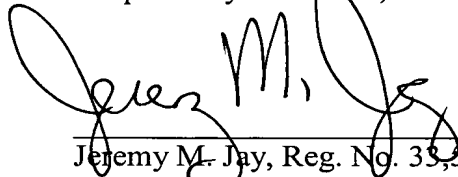
**5. Fee Payment**

- ☐ Attached is a check in the sum of \$  
☐ Charge Account No. 12-1216 the sum of \$ . A duplicate of this transmittal is attached.

**6. Fee Deficiency**

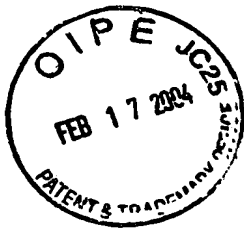
- ☒ If any additional fee is required in connection with this communication, charge Account No. 12-1216. A duplicate copy of this transmittal is attached.

Respectfully submitted,



Jeremy M. Jay, Reg. No. 33,587  
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700 Thirteenth Street, N.W., Suite 300  
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(202) 737-6770 (telephone)  
(202) 737-6776 (facsimile)

Date: 17 Feb. 2004



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Dear Sir:

In response to the Examiner's Answer mailed February 2, 2004, Appellants submit this Reply Brief.

*Argument*

Appellants' brief, filed January 5, 2004, explains why one of ordinary skill in the art reading Pall '070, that discloses fibrous red cell barrier/leukocyte depletion media and membranes in separate devices, would not be led to combine the media into a single device (in effect, combining both devices into a single device), and would not be led to process a biological fluid by passing it through such a device.

An Examiner's Answer was mailed on February 2, 2004.

In re Appln. of BORMANN et al.  
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The Examiner's Answer states (page 9):

The present case is about a single reference and whether there is any explicit or implied suggestion to combine the filters [disclosed in Pall '070] into one housing. Re explicit or implied suggestions to combine, Pall '070 teaches a system combining the elements recited in the claim (see abstract).

The Answer then goes on (page 9) to quote sections of Pall '070. However, these sections do not provide either explicit or implied suggestions to combine the filter media in a single housing.

For example, the Answer quotes as follows from Pall '070: "filter assembly . . . in a suitable housing . . ." The full sentence in Pall '070 actually states "As used herein, filter assembly refers to the porous medium positioned in a suitable housing" (col. 6, lines 66-67; emphasis added).

Thus, the quoted section refers to a single medium, rather than a plurality of filter media, and fails to provide an explicit or implicit suggestion leading one to the claimed invention.

The Answer then goes on to quote as follows: ". . . filter assembly may include a leukocyte depletion medium, red cell barrier, . . . , porous medium may be configured as flat sheet, . . . hollow fiber, . . . , separation medium. . ."

Pall '070 actually states, for example, "An exemplary filter assembly may include a leucocyte depletion assembly or device or a red cell barrier assembly or device" (col. 7, lines 1-3; emphasis added) and "The porous medium may be configured as a flat sheet, a corrugated sheet, a web, or a membrane. The porous medium may be pre-formed, and configured as hollow fibers, although it is not intended that the invention should be limited thereby" (col. 7, lines 8-11; emphasis added). The discussion regarding separation is in a separate section (beginning at col. 7, line 13). Again, these sections refer to separate media in separate devices, and provide neither an explicit suggestion, nor an implied suggestion, to combine the separate media in a single housing.

In re Appln. of BORMANN et al.  
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The Answer states (page 8) “if one put the entire assembly of the Pall ref. (fig. 2) in one box and provide an inlet and an outlet to the box, it would read into the claims.”

The Answer provides no suggestion (explicit or implied) in Pall ‘070 of putting the embodiment of a biological fluid processing system illustrated in Figure 2 into a box, let alone a box with an inlet or an outlet. The Answer provides no explanation as to why one of ordinary skill in the art would do so, or how one would be able to add this “inlet” and “outlet” to “the box” and operate the system.

The Answer states (page 8) “a perpendicular flow leukocyte depletion/red cell barrier medium could be fitted into a housing which has a tangential flow membrane filter by simple engineering design” (emphasis added).

This “could” standard is untenable, since “[t]he mere fact that the prior art could have been so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.” *In re Laskowski*, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989) (quoting *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Put another way, the standard for obviousness “is not what . . . could have [been] done, but what . . . would have ‘been obvious’ . . . to do.” *Ex parte Marinaccio*, 10 USPQ2d 1716, 1717 (Bd. Pat. App. and Int. 1989; emphasis added).

For the reasons set forth above (and in the Appeal Brief, which is incorporated by reference herein), the prior art does not suggest the desirability of the modification. Moreover, the Answer does not explain how this “simple engineering design” would produce an operable device.

The Answer concludes by stating (page 10) “[i]t may also be noted that making integral, as combining the filters into one housing, would be an obvious engineering choice” (citing *In re Larson*, 144 USPQ 347, 349 (CCPA 1965)). Appellants submit there is no basis for the Answer’s use the term “integral” (or providing such a definition) in the context of the claimed invention. However, with respect to combining filters into a housing, for the reasons stated above, the cited art fails to suggest the desirability of the modification, and the Answer has failed to demonstrate this would be an obvious engineering choice.

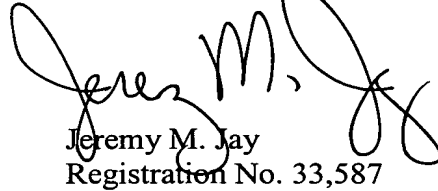
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Conclusion

The subject matter of the appealed claims is neither taught nor suggested by the cited references and is clearly unobvious over the prior art. Accordingly, Appellants respectfully submit that the rejections of the pending claims are improper and should be reversed.

Respectfully submitted,

LEYDIG, VOIT & MAYER



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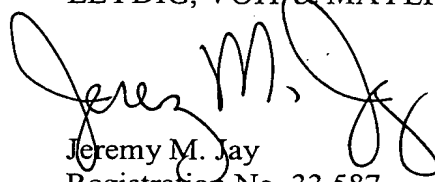
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